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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GROSS, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,475	TEREBA ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,21,27,28,32-37 and 40* is/are pending in the application.

4a) Of the above claim(s) *3-5,21,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,32-37,40* is/are rejected.

7)☒ Claim(s) *3-5,21,27 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1,3-5,21,27,28,32-37,40 are pending. Claim 2, 6-20,22-26,29-31,38-39,41-43 are canceled. Claims 3-5,21,27,28 are withdrawn. Claims 1, 32-37 and 40 are examined herein.

Information Disclosure Statement

2. The information disclosure statement filed 10/27/2003 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, specifically citations BN, BO, and BP. It has been placed in the application file, but the information referred to therein regarding citations BN, BO, and BP has not been considered.

3. The information disclosure statement filed 10/27/2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because citations CB,CC,CH,CI, CK, CV and CW pertain to web addresses (URLs), for which verification of the publication date is impossible. It has been placed in the application file, but the information referred to therein regarding citations CB,CC,CH,CI, CK, CV and CW has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all

certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

4. The information disclosure statement filed 9/17/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible *complete* copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein regarding Australian patent no. 707115 and Brinker et al. has not been considered.

5. The information disclosure statement filed 10/27/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein regarding European patent number 0837871 A has not been considered.

6. The information disclosure statement filed 10/27/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible *complete* copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein regarding Ausubel et al. has not been considered.

Priority

7. This application is a DIV of 09/377,986 filed 8/20/1999 (now PAT 6673631) which is a CIP of 08/785097 filed 1/21/1997 (now PAT 6027945).

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, however applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/785097, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior application 08/785097 does not disclose extraction of DNA from blood stained paper (solid-support). *Accordingly, claims 34 and 40 are not entitled to the benefit of application 08/785097.*

Claim Objections

8. Claims 3-5, 21,27 and 28 are dependent on a canceled claim and are hereby withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Makowski et al. (1997 J. Clinical Laboratory Analysis 11:87-93).

The claimed invention is drawn to a method of isolating DNA target material from a solid support, the method comprising: contacting the solid support containing the DNA target material with a chaotropic salt solution at a temperature of about 60 degree C to about 100 degree C thereby isolating at least a portion of the DNA target material from the solid support.

Makowski et al, throughout the publication and especially figure 1 and the abstract, teach utilizing a filter paper impregnated with guanidine thiocyanate. When dry blood samples containing DNA are collected on said paper and the paper is incubated in water at 95 degree C, a chaotope solution is formed *in situ* and the DNA is extracted from the paper into the liquid milieu. The guanidine thiocyanate of Makowski et al read on the chaotrope of claim 40. The filter paper of Makowski et al reads on the solid-support of claim 40. The temperature used by Makowski et al is in the range of claim 40.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1,32 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hornes et al** (US Patent 5512439) in view of **Boom** et al (IDS entry 10/27/2003 - 1990 J. Clinical Microbiology 28:495-503).

The claimed invention is drawn to a method for isolating a defined quantity of a DNA target material from other material in a medium by: a. providing a medium including the DNA target material; b. providing a discrete quantity of a silica-containing solid support capable of reversibly binding a definable quantity of the DNA target

material; c. forming a complex of the silica-containing solid support and the DNA target material by combining the silica-containing solid support and the medium; d. removing the complex with the DNA target material from the medium; and e. separating the DNA target material from the complex, whereby a defined quantity of the DNA target material is obtained. Claim 32 concerns a kit thereof and claims 35-37 represent variations of said kit.

Hornes et al teach, throughout the publication and especially example 6, hybridizing specific oligonucleotides on derivatived DYNABEADS from cell lysate. The lysate of Hornes et al is taken as 'providing the medium including the DNA target material' of claim 1, step a. The DYNABEADS of Hornes et al is taken to be 'providing a solid support capable of reversibly binding DNA target' of claim 1, step b. The hybridization of Hornes et al is taken to be 'forming the complex of the solid support and the DNA target material by combining the solid support and the medium' per claim 1, step c. The DYNABEADS of Hornes et al are *magnetic* and can be collected (aggregated) with a magnet (column 2, lines 25-31), which is taken as 'removing the complex with the DNA target material from the medium' of claim 1, step d.

Hornes et al describe elution of the DNA from the DYNABEADS in column 16 lines 20-23, which is taken to be 'separating the DNA target material from the complex' of claim 1, step e.

In column 16 lines 10-51, Hornes et al teach DYNABEADS as having a derivatization capacity of 390 pmol/mg, of which 250 pmol/mg is loadable with biotin-$d(T)_{25}$. Hornes et al. determined the ultimate hybridization capacity of oligo$(dA)_{25}$ with

biotin-d$(T)_{25}$ derivatized DYNABEADS as 193 pmol/mg. The measurements of Hornes et al were determined radiometrically and rigorously provides the 'discrete quantity' found in claim 1, step b and the 'defined quantity of DNA target material' of steps b and e, of claim 1.

Hornes et al teach a DNA binding kit in column 12, lines 5-11, which is taken to be the kit of claim 32. Hornes et al teach hybridizing the DNA in the presence of LiCl and a wash solution, in column 16, lines 10-23 which is taken to be the chaotrope of claim 35 and 36 and wash solution of claim 37. The magnetic particles of Hornes et al are suspended in solution per the examples provided.

Hornes et al does not teach *silica* particles, however.

Boom, et al throughout the document and especially page 495 second paragraph and the abstract, teach silica beads for binding nucleic acids in the presence of a chaotrope.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to substitute the DYNABEADS of Hornes et al for the silica particles of Boom et al.

One of ordinary skill in the art would have been motivated to make and use silica per Boom et al. in lieu of DYNABEADS of Hornes et al for the ability to bind DNA in raw clinical samples such as urine and human serum. One of ordinary skill in the art would have recognized the advantages of processing raw clinical samples including, the minimization of possible transmission between separate specimens and abating the risk

associated with potentially handing dangerous pathogens, both of which are noted by Boom et al on page 495.

One of ordinary skill would have measured the oligonucleotide loading capacity of the silica beads of Boom et al using the exacting radiometric precision demonstrated by Hornes et al with a reasonable expectation of success since radiometric counting is well known in the art to be very precise.

11. Claims 1,32-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hornes et al** (US Patent 5512439) in view of **Gocke** et al (US Patent 6156504).

The claimed invention is drawn to a method for isolating a defined quantity of a DNA target material from other material in a medium by: a. providing a medium including the DNA target material; b. providing a discrete quantity of a silica-containing solid support capable of reversibly binding a definable quantity of the DNA target material; c. forming a complex of the silica-containing solid support and the DNA target material by combining the silica-containing solid support and the medium; d. removing the complex with the DNA target material from the medium; and e. separating the DNA target material from the complex, whereby a defined quantity of the DNA target material is obtained. Claim 32 concerns a kit thereof and claims 33,35-37 represent variations of said kit.

Hornes et al is relied on as above. Hornes et al does not teach *silica* particles or liquid blood, however.

Gocke, et al throughout the document and especially column 6 lines 20-27, teach a preferred embodiment concerning extracellular nucleic acid extraction from blood plasma onto silica.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to utilize the radiometric measurements of Hornes et al to better characterize the silica particles per Gocke, et al.

Gocke et al teach in column 20, lines 43-50 that nucleic acids lying outside of the cell represent unique markers for cancer. In an effort to establish the concentration of such cancer markers, one of ordinary skill in the art would have been motivated to analyze the extracellular DNA extracted onto silica particles per Gocke et al, making and using the quantitative methodology of Hornes et al.

One of ordinary skill would have measured the oligonucleotide loading of the derivatized particles of Gocke et al using the exacting radiometric precision demonstrated by Hornes et al with a reasonable expectation of success since radiometric counting is well known in the art to be very precise.

12. Claims 1,32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hornes et al** (US Patent 5512439) in view of **Bienhaus** et al (US Patent 5746978).

The claimed invention is drawn to a method for isolating a defined quantity of a DNA target material from other material in a medium by: a. providing a medium including the DNA target material; b. providing a discrete quantity of a silica-containing solid support capable of reversibly binding a definable quantity of the DNA target

material; c. forming a complex of the silica-containing solid support and the DNA target material by combining the silica-containing solid support and the medium; d. removing the complex with the DNA target material from the medium; and e. separating the DNA target material from the complex, whereby a defined quantity of the DNA target material is obtained. Claim 32 concerns a kit thereof and claims 32-37 represent variations of said kit.

Hornes et al is relied on as above. Hornes et al does not teach silica particles or blood from a solid support, however.

Bienhaus, et al throughout the document and especially column 2 lines 6 & 45 and column 3 line 1 teach a preferred embodiment concerning a closed device for extracting nucleic acid samples from blood and other materials, including solids via silica beads. The solid sample is taken as the solid-support of claim 34.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to employ the methodology of Hornes et al with the DNA extraction machine of Bienhaus, et al

One of ordinary skill in the art would have been motivated to make and use the methodology of Hornes et al with the machine of Bienhaus, et al to avoid potential contamination from foreign nucleic acids as noted by Bienhaus et al in column 1, line 34.

One of ordinary skill would have measured the oligonucleotide loading capacity of the derivatized beads in the machine of Bienhaus et al using the exacting radiometric

precision demonstrated by Hornes et al with a reasonable expectation of success since radiometric counting well known in the art to be very precise.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1 and 40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16 and 27 of U.S. Patent No. 6673631.

Although the conflicting claims are not identical, they are not patentably distinct from each other because cliam 1, drawn to a method for isolating a defined quantity of DNA target material from a *silica-containing* solid support (genus), of the instant invention, is anticipated by the method for isolating a defined quantity of DNA target

material from *porous silica magnetic particles* (species) of claim 1 of U.S. Patent No. 6673631. The instant invention genus of claim 1 is also anticipated by the method for isolating a defined quantity of DNA target material from *porous silica magnetic particles with a mixture comprising a chaotropic salt* (species) of claim 16 of U.S. Patent No. 6673631.

Although the conflicting claims are not identical, they are not patentably distinct from each other because, claim 40, drawn to a method of isolating DNA target material from a solid support with a chaotrope mixture and temperature of about 60-100 degrees C, thereby isolating *at least a portion of the DNA target material* (genus), of the instant invention, is anticipated by the of method isolating DNA target material from a solid support *whereby a defined quantity of the DNA target material is obtained* (species) of claim 27 of U.S. Patent No. 6673631.

Conclusion

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher M Gross
Examiner
Art Unit 1639

cg

Mark Shibuya
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